

Please amend claim 3 to read as follows:

C2. 3. (once amended) A composition of claim 1 wherein said fibrate is fenofibrate.

Please amend claim 11 to read as follows:

C3 11. (once amended) A composition of claim 1 further consisting essentially of a co-solvent.

### Remarks

#### The Present Invention

The present invention is directed to a formulation consisting essentially of a fibrate dissolved in at least one oil and an emulsifier or emulsifier blend that is capable of forming an emulsion upon dilution in an aqueous medium.

#### The Office Action

The Office Action made the following rejections:

1) claims 2-6 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite; and

2) claims 1-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Krueger et al. in view of Suzuki et al. and The Merck Index.

#### Discussion of 35 U.S.C. §112, Second Paragraph Rejection

The Examiner has rejected claims 2-6 under 35 U.S.C. §112, second paragraph, as being indefinite.

Applicants have cancelled claims 2 and 4-6 and have amended claim 3 so that it is dependent on claim 1. Accordingly, this rejection no longer applies and should be withdrawn.

#### Discussion of 35 U.S.C. §103(a) Rejection

The Examiner has rejected claims 1-12 under 35 U.S.C. §103(a) as being unpatentable over Krueger et al. in view of Suzuki et al. and The Merck Index

The present invention is significantly different than those compositions described by Krueger et al. Krueger et al. teach an emulsion composition delivery system comprising a "suspension" of a lipid-regulating agent (p-hexadecylaminobenzoic acid sodium salt), sesame oil, and an emulsifier (page 1, lines 17-22; Example 5, page 15, lines 25-34; as a preferred composition on page 4, lines 19-24; and on page 6, lines 14 and 15). The present invention teaches solubilization of a lipid-regulating agent in at least one oil with one or more emulsifiers. The two compositions are physically very different (i.e., an emulsion-based suspension vs. an emulsified solution).

The Examiner states that it would have been obvious to employ a co-solvent in the oil-in-water emulsion composition of Krueger et al. presumably to improve the solubility of the lipid-regulating agent. However, based on Krueger et al. one skilled in the art would not be motivated to use a co-solvent (for solubilization) because Krueger et al. teaches compositions that are in the form of a "suspension of the drug" (page 4, line 20 of the cited reference).

The deficiencies of Krueger et al. are not cured by Suzuki et al. Suzuki et al. teach the use of antihyperlipidemic agents in general, and the use of the particular lipid-regulating agents, pravastatin and derivatives thereof, in an oil-in-water emulsion composition (page 4, line 58). The lipid-emulsion composition disclosed by Suzuki et al. comprises: (a) an oil component; (b) an emulsifying agent containing yolk lecithin and/or soybean lecithin; and (c) water; wherein said lipid emulsion comprises citric acid or a pharmaceutically acceptable salt thereof and at least one member selected from the group consisting of methionine, phenylalanine, serine, histidine, and pharmaceutically acceptable salts thereof (claim 1, page 41).

Claim 1, the sole independent claim of the present application has been amended to provide that the composition consists essentially of a fibrate dissolved in at least one oil and certain specified emulsifiers. Thus, the use of citric acid and amino acids are excluded from the scope of the claims. In view of the above comments, it is submitted that the combination of Krueger et al. in view of Suzuki et al. and The Merck Index does not render obvious claims 1, 3 and 7-12 as presently amended. Withdrawal of this rejection is respectfully requested.

Conclusion

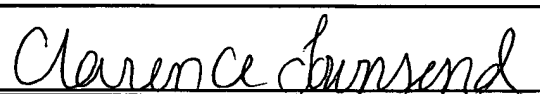
Applicants respectfully request favorable consideration and allowance of claims 1, 3 and 7-12 as presently amended. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 04-1644.

Respectfully submitted,

By   
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CERTIFICATE OF HAND DELIVERY	
I hereby certify that this Preliminary Amendment, and any other documents referred to as enclosed herein, is being deposited with the United States Postal Service, "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated below and addressed to Assistant Commissioner for Patents, Box CPA, 2900 Crystal Drive, Arlington, VA 22202-3500.	
Express Mail Label No.:	EL865233859US
Date of Deposit:	November 26, 2001
Typed/Printed Name of Person Signing:	Clarence Townsend
Signature:	

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

In the Claims

Claim 1 is amended as follows:

1. (twice amended) A composition [comprising] consisting essentially of a fibrate dissolved in at least one oil with one or more emulsifiers, selected from the group consisting of polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, d-alpha tocopheryl polyethylene glycol 1000 succinate and combinations thereof wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.

Claim 3 is amended as follows:

3. (once amended) A composition of claim [2] 1 wherein said fibrate is fenofibrate.

Claim 11 is amended as follows:

11. (once amended) A composition of claim 1 further [comprising] consisting essentially of a co-solvent.